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10/828,699

04/21/2004

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EXAMINER

GILBERT, ANDREW M

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/828,699  
Filing Date: April 21, 2004  
Appellant(s): CHEVES ET AL.

\_\_\_\_\_  
Jason W. Burgmaier, Reg. No. 57,222  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 2/25/2011 appealing from the Office action mailed 9/8/2010.

**(1) Real Party in Interest**

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The following is a list of claims that are rejected and pending in the application:  
15, 26-33.

**(4) Status of Amendments After Final**

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief. The Amendment filed 11/08/2010 after the Final Rejection of 9/8/2010 was entered as discussed in the Advisory Action mailed on 11/23/2010.

**(5) Summary of Claimed Subject Matter**

The examiner has no comment on the summary of claimed subject matter contained in the brief.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being

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maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

**(7) Claims Appendix**

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

**(8) Evidence Relied Upon**

2004/0243156

Wu et al.

12-2004

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 15, 26-33 are rejected under 35 U.S.C. 102(e) as anticipated by Wu et al (2004/0243156).

The applied reference has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art

under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

2. Wu et al discloses a cutting balloon catheter (Fig 2), comprising: an elongate catheter shaft (12); a balloon (114) coupled to the shaft, the balloon having a first fully inflated configuration and a second non-inflated configuration (Fig 2-4), wherein the balloon has a plurality of substantially smooth wings formed therein when in the second non-inflated configuration (Fig 2-4; [0030]), a metallic cutting blade (16) for severing or breaking up a lesion adhesively bonded ([0018]) to the balloon throughout the entire use of the cutting balloon catheter (Fig 2-4; Summary), the cutting blade including means for cutting having two intersecting planes which form a cutting edge, including means for gripping thereon and having a longitudinal axis (16; Fig 2-4), and having a cross-sectional shape that is substantially triangular in a plane traverse to the longitudinal axis (16; Fig 2-4); wherein the means for cutting and means for gripping are defined by a series of undulations (16; Fig 2; wherein the cutting members shown have matching waves as waves 44 on wings 42) on the cutting blade in the first fully inflated configuration; and wherein the undulations curve from side-to-side relative to the longitudinal axis in the first inflated configuration (16; Fig 2; wherein the cutting members shown have matching waves as waves 44 on wings 42); the wings are a plurality of alternating inward/outward radial deflections in the balloon that are evenly spaced circumferentially around the balloon (Fig 3); where there are 4 wings (Fig 3); a plurality

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of cutting members at the inward-most positions of respective pairs of adjacent wings (Fig 3); where the wings fold over and cover the metallic cutting blade members ([0017]); the cutting blade has a textured surface (16; with regards to claims 32 and 33 the Examiner has interpreted "textured" to mean the visual or tactile surface characteristics and appearance of something (see Webster's dictionary definition). Thus, the undulating cutting member shown in Fig 4 inherently has a textured surface).

#### **(10) Response to Argument**

- 1. The Appellant argues that the Examiner admitted in the Final Office Action mailed on 9/8/2010, ¶7 that "Wu is silent regarding any undulations of the blades when the balloon is inflated" and consequently, this admission evidences that the 35 U.S.C. § 102(e) is inappropriate. (Br. at 5, ¶5 - 6, ¶1).**

The Examiner respectfully disagrees. First, claims 15, 26-33 were rejected in the Final Rejection mailed on 9/8/2010 under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wu et al (2004/0243156) (emphasis added). The Examiner contends that the statement "Wu is silent regarding any undulations of the blades when the balloon is inflated" was made in reference to the § 103(a) rejection and not the § 102(e) rejection. The § 103(a) rejection was withdrawn in the Advisory Action mailed on 11/23/2010 in response to Appellant's showing of common ownership between Wu et al and the present application pursuant to the provisions of § 103(c). Second, the statement "Wu is silent regarding any undulations of the blades when the balloon is inflated" is not evidence that Wu does not teach the limitation. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

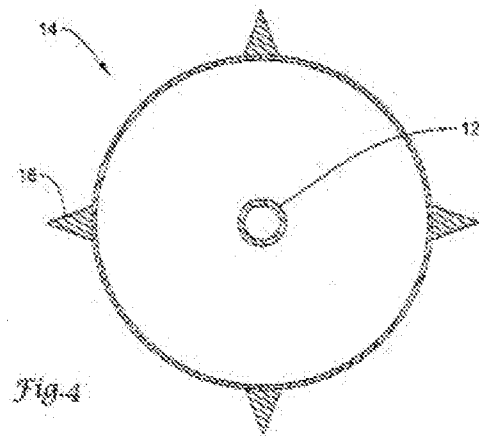
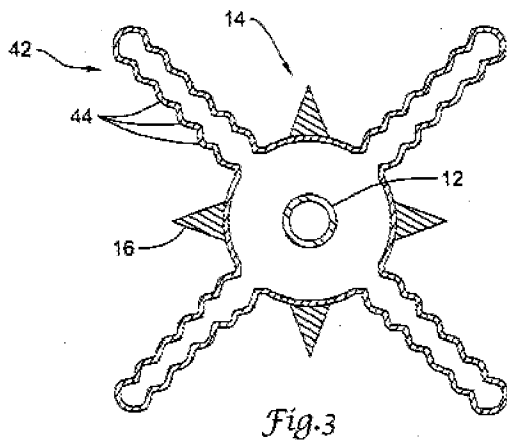
M.P.E.P. § 2131, quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). As will be discussed and shown below, Wu teaches undulations of the blade when the balloon is inflated. Thus, contrary to the Appellant's argument, the Board must not consider this statement an admission or evidence relevant to the issues of the present appeal.

- 2. The Appellant argues that Wu et al. does not teach “wherein the means for cutting and means for gripping are defined by a series of undulations on the cutting blade in the first fully inflated configuration” because Fig 3 of Wu shows the undulations (44) of the wings (42), when the balloon is deflated, while Fig 4 of Wu shows an absence of those undulations when the balloon is inflated (Wu at ¶ 0034). Thus, Appellant argues that it is likely that in the inflated state, the cutting members would extend longitudinally along a straight path, without any undulation, as there would be no wings (42), and thus no undulating surface (44) that the cutting members would match. (Br. at 6, ¶4-5).**

The Examiner respectfully disagrees. First, the Examiner notes that the balloon (14) is formed of flexible/pliable material (¶20) allowing the balloon to inflate/deflate and wings shown in Fig 3 (see below) to fold and re-fold into a low profile configuration over the cutting members (16) during movement through a blood vessel to shield the vessel from the cutting members to prevent tissue damage (¶17). In stark contrast, the cutting members are a rigid blade structure configured for cutting into tissue, such as a lesion (¶18). The “cutting members 16 may include a metallic cutting blade that is similar to a knife” (¶18; emphasis added). Fig 3 and Fig 4 of Wu show a single cross-section taken from line “3-3” in Fig 2 in a deflated/inflated configuration respectively. These Figures do not show, or purport to show, the longitudinal configuration of blades (16) along the length of the balloon; rather, they show just a cross-section. From Fig 3 and Fig 4, one

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of ordinary skill in the art cannot determine that the cutting blades (16) are oriented longitudinally in a straight line, without any undulation. But, one of ordinary skill in the art can determine from the full disclosure of Wu that the balloon is a flexible, pliable material whose purpose is to inflate/deflate and have wings that fold and re-fold over cutting members which are a metallic and similar to a knife and with a purpose of cutting into tissue.



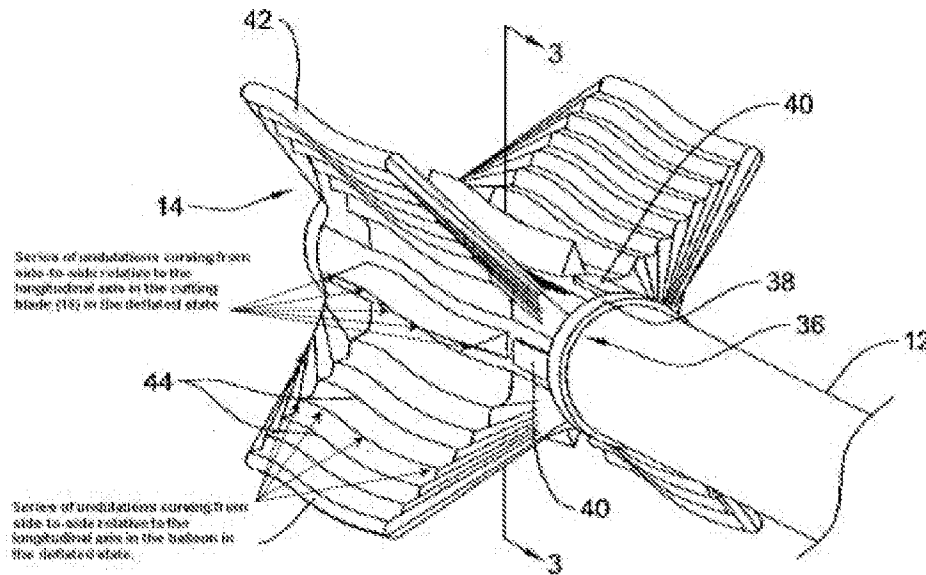


Fig. 2

Thus, contrary to Appellant's assertions, one of ordinary skill in the art would not find it likely that in the inflated state, the cutting members would extend longitudinally along a straight path, without any undulation, as there would be no wings (42), and thus no undulating surface (44) that the cutting members would match. No, instead, one of ordinary skill in the art would find that the purpose of the undulations and wings of the balloon are entirely distinct from the purpose of cutting tissue for the cutting members and there is no expectation or reason for the undulating surface of the cutting members to match the structure of the balloon and wings in the inflated configuration. Wu et al teaches metallic, knife-like cutting blades (16) to sever tissue. In the inflated

configuration, a metallic, knife-like cutting blade would have the same undulating structure as the blades have shown in the deflated configuration in Fig 2.

Thus, the Board must find that Wu et al teaches “wherein the means for cutting and means for gripping are defined by a series of undulations on the cutting blade in the first fully inflated configuration” and affirm the Examiner’s rejection.

**3. The Appellant argues that the Examiner appears to rely, improperly, on an “expectation” of the rigidity of Wu’s blade to conclude that the undulations would remain when the balloon is inflated. (Br. at 6, ¶6 - 7, ¶1).**

The Examiner respectfully disagrees. Wu et al necessarily teaches either expressly or inherently, each and every element as set forth in the claims. Wu et al necessarily teaches that the cutting blades are rigid to conclude that the undulations would remain when the balloon is inflated. Wu et al teaches, as shown in the annotated Fig 2 above, that its cutting member (16) have undulations that curve from side-to-side relative to the longitudinal axis. The “cutting members 16 may include a metallic cutting blade that is similar to a knife” and are “configured for cutting into tissue such as a lesion (¶18; emphasis added). One of ordinary skill in the art at the time of the invention would recognize that in the inflated configuration the cutting blade (16) would retain undulations if it was to be configured for cutting into tissue as a metallic cutting blade that is similar to a knife. A metallic cutting blade that is similar to a knife configured to cut into tissue is necessarily and inherently rigid to retain the blade’s undulating structure between the deflated and inflated position. A metallic cutting blade that would not retain its rigid undulating structure in an inflated configuration would not be sufficiently configured to cut into tissue such as a lesion. The blade would lack the

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rigidity and stretch to perform such a cut if it did not retain its structure between a deflated and inflated configuration. The Examiner has relied upon Wu et al's explicit teachings as disclosed in Figs 2-4 and ¶¶17-18, 34 with the knowledge of one of ordinary skill in the art would recognize that a metallic, knife-like cutting blade configured to cut tissue would necessarily and inherently possess sufficient rigidity to maintain the cutting member (16) undulations as shown in Fig 2 in the inflated configuration.

Thus, the Board must find that the Examiner has relied on the express and inherent teachings of Wu et al, not an expectation, on the rigidity of Wu's blade to conclude that the undulations would remain when the balloon is inflated and affirm the Examiner's rejection.

- 4. The Appellant argues that Kelly (U.S. Pat. Pub. 2005/0028343) teaches that metal cutting blades, while mounted to a catheter balloon, may be able to bend or flex, such bending or flexing resulting in a cutting blade without a series of undulations in the fully inflated position. Thus, the Examiner is incorrect in relying upon an "expectation" and "inherency" argument to show that Wu anticipates the claim limitation. Because the blades of Wu do not necessarily possess the rigidity to ensure that the undulations of the blade would remain when the balloon is inflated, the rejection under § 102(e) is improper. (Br. at 7-9).**

The Examiner respectfully disagrees. The Examiner has shown in (1)-(3) above that the extrinsic evidence contained in the disclosure of Wu et al either expressly or inherently describes every element as set forth in the claim to anticipate the claims under § 102(e). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency,

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however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). The Examiner has provided explicit factual and technical reasoning (see (1)-(3)) to support that Wu necessarily teaches every element of the claims.

Once a reference teaching the product appears to be substantially identical is made the basis of a rejection, and the Examiner presents evidence or reasoning tending to show inherency, the burden shifts to the applicant to shown an unobvious difference. M.P.E.P. § 2112(V). "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on 'prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

- a. **The Appellant has not met his burden of proof to show an unobvious difference because Kelly (U.S. Pat. Pub. 2005/0028343) is substantially different in material and structure than Wu et al.**

Appellant cites Kelly as evidence that cutting blades formed of metal may be able to bend or flex while mounted to the balloon so Wu cannot necessarily possess the rigidity to ensure that the undulations of the blade would remain when the balloon is inflated. Br. at 8, ¶1. Kelly is not structurally similar enough to Wu et al to act as evidence that the cutting blades of Wu et al necessarily or inherently possess the rigidity to ensure that the undulations of the blade would remain when the balloon is inflated.

As the Examiner noted in the Final Rejection mailed on 9/8/2010, pg 7, ¶8, the Kelly reference is not the Wu reference and no teachings of Kelly may be used to contradict the explicit teachings in Wu as cited by the Examiner in sections (I)-(III) above. Also, Kelly does not represent or disclose well known teachings in the pertinent art. Kelly is simply one reference cherry-picked by the Appellant to attempt to support the argument. But, even while cherry-picked, Kelly fails to provide any evidence showing an unobvious difference between Appellant's claims and Wu et al to meet the Appellant's burden of proof because Kelly is substantially different in material and structure than Wu et al.

Kelly's structure of the blade and attachment to the balloon is significantly and substantially different from Wu. For example, Kelly discloses varying blade rigidity. Kelly at ¶13. Unlike Wu, which explicitly requires a metallic, knife-like cutting blade configured to cut into tissue, Kelly discloses that the blade may comprise a plurality of materials, including polymers. *Id.* Kelly discloses using a joining member (38) to attach the blade to the balloon. *Id.* at ¶12. The joining member may be soft and generally flexible - and made elastic or pliable. *Id.* at ¶22. Accordingly, Kelly teaches that though the joining

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member connecting the cutting member (20) and the balloon (16), that cutting member (20) maybe move laterally up to eight degrees. *Id.* There is no evidence disclosed in Kelly that the cutting member (20) itself flexes. No, what Kelly teaches is that the joining member (38) provides a flexible and bendable connection between the cutting member and the balloon. Additionally, Wu does not use or require a joining member. Instead, Wu uses an adhesive to attach the blade to the balloon. Thus, Kelly teaches flexibility and bending of a blade via a joining member that attaches the blade to the balloon; whereas Wu explicitly discloses a metallic, knife-like rigid blade attached directly to the balloon via adhesive.

One of ordinary skill in the art at the time of the invention would find that Kelly is substantially different in material and structure regarding the cutting member and its attachment to the balloon. Kelly does not provide evidence supporting the Appellant's assertion that the undulations in Wu's blade would not necessarily remain in the blade when balloon is fully inflated. Thus, the Board must find that Kelly is substantially different in material and structure from Wu and does not provide evidence supporting the Appellant's assertion that the undulations in Wu's blade would not necessarily remain in the blade when balloon is fully inflated. Because Wu et al necessarily teaches the Appellant's claims as discussed in (1)-(3) the Board must affirm the Examiner's rejection.

#### **(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Andrew M Gilbert/

Examiner, Art Unit 3767

Conferees:

/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767

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